IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Aaron GARZON et al.	Confirmation No.: 9969
Application No.: 10/602,745	Patent No.: 7,235,584 B2
Filing Date: June 25, 2003	Patent Date: June 26, 2007
For: NON-PSYCHOTROPIC CANNABINOIDS	Attorney Docket No.: 87754-7499

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 C.F.R. § 1.322

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Patentees hereby respectfully request the issuance of a Certificate of Correction in connection with the above-identified patent. The corrections are listed on the attached Form PTO-1050. The corrections requested are as follows:

Column 59:

Line 43 (claim 6, line 11), before "optionally further substituted" change "terrahydropyran," to -- tetrahydropyran, --. Support for this change appears in application claim 6.

Column 62:

Line 4 (claim 15, line 13), before "alkyloxy" change "$C_{,1-6}$" to -- C_{1-6} --. Support for this change appears in application claim 15.

Line 30 (claim 19, line 4), after "solution prepared" change "wit" to -- with --. Support for this change appears in application claim 19.

The requested corrections are for errors that appear to have been made by the Office. Therefore, no fee is believed to be due for this request. Should any fees be required, however,

please charge such fees to Winston & Strawn LLP Deposit Account No. 50-1814. Please issue a Certificate of Correction in due course.

Respectfully submitted,

7-10-07

Date

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212-294-3311

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO.: 7,235,584 B2
APPLICATION NO.: 10/602,745
DATED: June 26, 2007
INVENTOR(S): Garzon et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 59:
Line 43 (claim 6, line 11), before "optionally further substituted" change "terrahydropyran," to -- tetrahydropyran, --.

Column 62:
Line 4 (claim 15, line 13), before "alkyloxy" change "$C_{,1-6}$" to -- C_{1-6} --.
Line 30 (claim 19, line 4), after "solution prepared" change "wit" to -- with --.

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substituted at the terminal carbon atom by a phenyl group, or (c) —$(CH_2)_nOR'''$ wherein n is an integer of 1 to 7 and R''' is hydrogen or C_1–C_6 alkyl;

with the proviso that R_1 is other than a heterocyclic moiety having a labile hydrogen atom so that said moiety acts as a carboxylic acid analogue.

2. The compound according to claim **1** wherein R_1 is a saturated or unsaturated cyclic moiety, an aromatic moiety or a heterocyclic moiety having from 5–20 atoms comprising one or two-ringed structures, wherein each ring comprises 3–8 carbons and 0–4 heteroatoms, said heteroatoms each independently selected from the group consisting of N, O, and S; optionally further substituted with at least one substituent selected from the group consisting of lower alkyl, halogen, nitro, cyano, —SR''', —NHR''', —$N(R''')_2$, —OR''', —COR''', —C(O)OR''' or NH—CUR''' moiety wherein R''' is hydrogen or C_1–C_6 alkyl.

3. The compound according to claim **1** wherein R_1 is a heterocyclic moiety selected from the group consisting of an imidazolyl, an imidazolinyl, a morpholino, a piperidyl, a piperazinyl, a pyrazolyl, a pyrrolyl, a pyrrolidinyl, a triazolyl, and a tetrazolyl, optionally further substituted wherein the substituent is selected from the group consisting of C_{1-6} alkyl, C_{1-6} alkyloxy, C_{1-6} alkylthio, keto, carboxy, or nitro, wherein C_{1-6} alkyl, C_{1-6} alkoxy and C_{1-6} alkylthio are intended to include saturated and unsaturated linear, branched and cyclic structures.

4. The compound according to claim **1** wherein R_1 is imidazolyl, pyrazolyl, 2-methyl thio-2-imidazolinyl, or 4-methylpiperidinyl.

5. The compound according to claim **1** wherein A—B is a 6(1) double bond and G is —OH or lower acyloxy.

6. The compound according to claim **5** wherein R_2 is 1,1-dimethylheptyl or 1,2-dimethylheptyl and wherein R_1 is selected from the group consisting of imidazole, pyrazole, oxazole, isoxazole, tetrahydropyridine, pyrazoline, oxazoline, pyrrolidine, imidazoline, 2-thio-imidazole, 2-methylthio-imidazoline, 4-methyl-2-imidazoline, 4,4-dimethyl-2-imidazoline, methyl sulfide, methylsulfoxide, acetamido, benzamide, cyano, 1,2,4-triazole, 1,3,4-triazole, 1,2,3,4-tetrazole, 1,2,3,5-tetrazole, thiophene, phenyl, morpholine, thiomorpholine, thiazolidine, glycerol, piperazine, piperidine and terrahydropyran, optionally further substituted wherein the substituent is selected from the group consisting of C_{1-6} alkyl, C_{1-6} alkyloxy, C_{1-6} alkylthio, keto, carboxy, or nitro, wherein C_{1-6} alkyl, C_{1-6} alkoxy and C_{1-6} alkylthio are intended to include saturated and unsaturated linear, branched and cyclic structures.

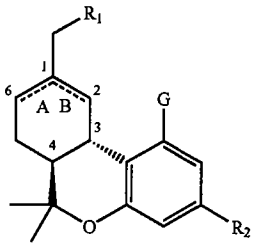
7. The compound according to claim **6** wherein R_1 is imidazole, pyrazole, 2-methyl thio-2-imidazoline, or 4-methylpiperidine.

8. The compound according to claim **1** wherein A—B is absent and G is —OH or lower acyloxy.

9. The compounds according to claim **1** selected from the group consisting of: (+)-(3 S,4 S)-6,6-Dimethyl-(1,1 -dimethylheptyl)-1-hydroxy-9- (imidazolomethyl)-6a,7,10,10a-tetrahydro-6H-dibenzo [b,d]pyran; (+)-(3S,4 S)-6,6-Dimethyl -dimethylheptyl)-1-hydroxy-9-(pyrazolomethyl)-6a,7,10,10a-tetrahydro-6H-dibenzo [b,d]pyran; (+)-(3S,4 S)-6,6-Dimethyl-(1,1-dimethylheptyl)-1-hydroxy-9-(1H-imidazol -2-ylsulfanyl methyl)-6a,7,10,10a-tetrahydro-6H-dibenzo [b,d]pyran; (+)-(3S,4S)-6,6-Dimethyl-(1,1-dimethylheptyl)-1-hydroxy-9-(4-piperidinopiperidine methyl)-6a, 7,10,10a-tetrahydro-6H-dibenzo[b,d]pyran; and (+)-(3S,4S)-6,6-Dimethyl-(1,1-dimethylheptyl) -1-hydroxy-9-(4-methylpiperidine methyl)-6a,7,10,10a-tetrahydro-6H-dibenzo [b,d]pyran.

tetrahydropyran,

10. A pharmaceutical composition comprising as an active ingredient a compound of the general formula (I):



having the (3S,4S) configuration and being essentially free of the (3R,4R) enantiomer, wherein A—B indicates an optional 1(2) or 6(1) double bond,

R_1 is

A) R_3 where R_3 is selected from the group consisting of

a) a linear or branched, saturated or unsaturated, carbon side chain comprising 1–8 carbon atoms and 1–3 heteroatoms, at least one heteroatom being placed between two carbon atoms; or

b) a saturated or unsaturated cyclic moiety or an aromatic or heterocyclic moiety having from 5–20 atoms comprising one or two-ringed structures, wherein each ring comprises 3–8 carbons and 0–4 heteroatoms, said heteroatoms each independently selected from the group consisting of N, O, and S; wherein each ring optionally is further substituted with one or more groups selected from

i) C_{1-6} alkyl,
ii) C_{1-6} alkoxy,
iii) C_{1-6} alkylthio,
iv) halo,
v) carboxyl,
vi) —CO_2—C_{1-4} alkyl,
vii) keto,
viii) nitro, and
ix) a saturated or unsaturated cyclic moiety, or an aromatic or a heterocyclic moiety comprising one or two ringed structures wherein each ring comprises 3–8 carbons and 0–4 heteroatoms, said heteroatoms each independently selected from the group consisting of N, O, and S;
wherein each ring optionally is further substituted with one or more groups selected from i)-viii) as defined above;

B) an amine or an amide substituted with at least one substituent as defined in R_3 above;

C) a thiol, a sulfide, a sulfoxide, a sulfone, a thioester or a thioamide optionally substituted with one substituent as defined in R_3 above; or

D) an ether —OR_3 wherein R_3 is as defined above;

G is (a) halogen, (b) C_1–C_6 alkyl, or (c) —OR wherein R is (a') —R", wherein R" is hydrogen or C_1–C_6 alkyl optionally containing a terminal —OR''' or —OC(O)R''' moiety wherein R''' is hydrogen or C_1–C_6 alkyl, or (b') —C(O)R''' wherein R''' is as previously defined, and

R_2 is (a) C_1–C_{12} alkyl, (b) —OR'''', in which R''''is a straight chain or branched C_2–C_9 alkyl which may be substituted at the terminal carbon atom by a phenyl group, or (c) —$(CH_2)_nOR'''$ wherein n is an integer of 1 to 7 and R''' is hydrogen or C_1–C_6 alkyl; with the proviso that R_1 is other than a heterocyclic moiety having a labile hydrogen atom so

that said moiety acts as a carboxylic acid analogue; together with a pharmaceutically acceptable diluent or carrier.

11. The composition according to claim **10** wherein R_1 is a saturated or unsaturated cyclic moiety, an aromatic moiety or a heterocyclic moiety having from 5–20 atoms comprising one or two-ringed structures, wherein each ring comprises 3–8 carbons and 0–4 heteroatoms, said heteroatoms each independently selected from the group consisting of N, O, and S; optionally further substituted with at least one substituent selected from the group consisting of lower alkyl, halogen, nitro, cyano, —SR'", —NHR'", —$N(R'")_2$, —OR'", —COR'", —C(O)OR'" or NH—COR'" moiety wherein R'" is hydrogen or C_1–C_6 alkyl.

12. The composition according to claim **10** wherein R_1 is a heterocyclic moiety selected from the group consisting of an imidazolyl, an imidazolinyl, a morpholino, a piperidyl, a piperazinyl, a pyrazolyl, a pyrrolyl, a pyrrolidinyl, a triazolyl, and a tetrazolyl, optionally further substituted wherein the substituent is selected from the group consisting of C_{1-6} alkyl, C_{1-6} alkyloxy, C_{1-6} alkylthio, keto, carboxy, or nitro, wherein C_{1-6} alkyl, C_{1-6} alkoxy and C_{1-6} alkylthio are intended to include saturated and unsaturated linear, branched and cyclic structures.

13. The composition according to claim **10** wherein R_1 is imidazolyl, pyrazolyl, 2-methyl thio-2-imidazolinyl, or 4-methylpiperidinyl.

14. The composition according to claim **10**, wherein A—B is a 6(1) double bond, and G is —OH or lower acyloxy.

15. The composition according to claim **14** wherein R_2 is 1,1-dimethylheptyl or 1,2-dimethylheptyl and wherein R_1 is selected from the group consisting of imidazole, pyrazole, oxazole, isoxazole, tetrahydropyridine, pyrazoline, oxazoline, pyrrolidine, imidazoline, 2-thio-imidazole, 2-methylthio-imidazoline, 4-methyl-2-imidazoline, 4,4-dimethyl-2-imidazoline, methyl sulfide, methylsulfoxide, acetamido, benzamide, cyano, 1,2,4-triazole, 1,3,4-triazole, 1,2,3,4-tetrazole, 1,2,3,5-tetrazole, thiophene, phenyl, morpholine, thiomorpholine, thiazolidine, glycerol, piperazine, piperidine and tetrahydropyran, optionally further substituted wherein the substituent is selected from the group consisting of C_{1-6} alkyl, C_{1-6} alkyloxy, C_{1-6} alkylthio, keto, carboxy, or nitro, wherein C_{1-6} alkyl, C_{1-6} alkoxy and C_{1-6} alkylthio are intended to include saturated and unsaturated linear, branched and cyclic structures.

16. The composition according to claim **15** wherein R_1 is imidazole, pyrazole, 2-methyl thio-2-imidazoline, or 4-methylpiperidine.

17. The composition according to claim **10** wherein A—B is absent and G is OH or a lower acyloxy group.

18. The composition according to claim **10** wherein the active ingredient is selected from the group consisting of: (+)-(3S,4S)-6,6-Dimethyl-(1,1-dimethylheptyl) -1-hydroxy-9-(imidazolomethyl)-6a,7,10,10a-tetrahydro-6H-dibenzo [b,d]pyran; (+)-(3S,4S)-6,6-Dimethyl-(1,1-dimethylheptyl)-1-hydroxy-9-(pyrazolomethyl)-6a,7,10,10a-tetrahydro-6H-dibenzo [b,d]pyran; (+)-(3S,4S) -6,6-Dimethyl-(1,1-dimethylheptyl) -1-hydroxy-9-(1H-imidazol-2-ylsulfanyl methyl)-6a,7,10,10a-tetrahydro -6H-dibenzo[b,d]pyran; (+)-(3S,4S)-6,6-Dimethyl-(1,1-dimethylheptyl)-1-hydroxy -9-(4-piperidinopiperidinemethyl)-6a,7,10,10a-tetrahydro-6H-dibenzo[b,d]pyran; and (+)-(3S,4S)-6,6-Dimethyl-(1,1-dimethylheptyl)-1-hydroxy-9-(4-methylpiperidine methyl)-6a,7,10,10a-tetrahydro-6H-dibenzo[b,d]pyran.

19. The composition according to claim **10** wherein the carrier or diluent is an aqueous cosolvent solution comprising a pharmaceutically acceptable cosolvent, a micellar solution prepared with natural or synthetic ionic or non-ionic surfactants, or a combination of such cosolvent and micellar solutions.

20. The composition according to claim **19** wherein the carrier is (a) a solution of ethanol, a surfactant, and water or (b) an emulsion comprising a triglycerides, lecithin, glycerol, an emulsifier, an antioxidant, and water.

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